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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/882,171 | 06/18/2001 | Steven M. Ruben | PZ002-P2C1 | 9197 |

22195 7590 11/17/2004
HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
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EXAMINER

MARTINELL, JAMES

| | |
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| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|--------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/882,171 | RUBEN ET AL. | |
| | Examiner | Art Unit | |
| | James Martinell | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, 14, 15, 18, and 21, drawn to nucleic acids, vectors, methods of making host cells, methods of making polypeptides, methods of diagnosis using nucleic acids, and genes, classified in class 536, subclass 23.5 and class 435, subclasses 252.3, 325, 6, 320.1, and 69.1.
- II. Claims 11, 12, and 16, drawn to polypeptides, classified in class 530, subclass 350.
- III. Claim 13, drawn to antibodies, classified in class 530, subclass 387.1.
- IV. Claim 17, drawn to methods of treatment using nucleic acids, classified in class 514, subclass 44.
- V. Claims 19 and 20, drawn to methods of diagnosis and methods of determining binding partners for polypeptides, classified in class 435, subclass 7.1.
- VI. Claim 22, drawn to methods of identifying biological activity, classified in class 435, subclass 7.1.
- VII. Claim 23, drawn to a product of the assay method of claim 20, classified in class unknown, subclass unknown.
- VIII. Claim 24, drawn to methods of treatment using polypeptides, classified in class 514, subclass 12.

The inventions are distinct, each from the other because of the following reasons. The nucleic acids, vectors, host cells, and genes of Group I are materially different from, and are therefore separate and distinct from the polypeptides of Group II, the antibodies of Group III, or the unknown "product" of Group VII. The methods of Group I are not needed to make the polypeptides of Group II, which polypeptides may be synthesized chemically or isolated from naturally occurring sources. The methods of Group I are not needed to make the antibodies of Group III. The methods of Group I are not needed to make the unknown "product" of Group VII. The methods of Groups I, IV, V, VI, and VIII may each be practiced independently of the other. The polypeptides of Group II are separate and distinct from the antibodies of Group III and the unknown "product" of Group VII. The polypeptides of Group II are not

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needed to practice the methods of Group IV and have uses other than in the methods of Groups V, VI, and VIII. For example, the polypeptides may be used as antigens or in affinity chromatography. The antibodies of Group III are not needed to practice the methods of any one of Groups IV, V, VI, or VIII. The antibodies of Group III are separate and distinct from the unknown "product" of Group VII. The "product" of Group VII is not needed to practice any of the methods of Groups IV, V, VI, or VIII. The "product" of Group VII is not defined by the methods of Group V.

Claims 1-10, 14, 15, 18, 21, and 24 are drawn to nucleotides, nucleotide constructs, and/or methods requiring the use of nucleotides or nucleotide constructs that contain more than one individual, independent, and distinct nucleotide sequence in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (November 19, 1996). This notice permits the examination of from one to ten independent and distinct nucleotide sequences in a single application based upon USPTO resources.

Applicant is required to select no more than ONE of the individual sequences for examination. The search of the no more than ONE selected sequence may include the complement of the selected sequence and, where appropriate, may include subsequences within the selected sequence (*e.g.*, oligomeric probes and/or primers).

Claims 11-13, 16, 17, 19, 20, and 22 are drawn to more than one unrelated, independent, and distinct polypeptide or methods requiring the use of more than one unrelated, independent, and distinct polypeptide. Should applicants elect any one or Groups II, III, V, or VIII for examination, applicants are further required to select one polypeptide or a set of methods that requires the use of only one polypeptide for examination on the merits.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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To search any two groups as outlined above would create an undue burden for the U.S. PTO because the searches of the non-patent literature are not only non-overlapping to any appreciable extent, but are also divergent in nature.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Reminder Regarding *In re Ochiai* and *In re Brouwer*

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.


PLEASE NOTE THE FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1631

11/13/04